

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2005/000760

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 A61M39/22 A61M39/24 A61M25/00

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	WO 97/23255 A (B.BRAUN CELSA; NADAL, GUY) 3 July 1997 (1997-07-03) page 6, line 26 - page 10, line 20; figures	1-6,8, 10-17
X	WO 97/26931 A (STINGER, FLORENCE) 31 July 1997 (1997-07-31) page 10, lines 2-4	10,14
Y	page 12, last paragraph - page 13, paragraph 2; figures	1-4,6,8, 10-17
Y	US 6 152 909 A (BAGAOISAN ET AL) 28 November 2000 (2000-11-28) column 13, paragraph 2	5
	----- -/--	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

\* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&amp;" document member of the same patent family

Date of the actual completion of the international search

27 April 2005

Date of mailing of the international search report

20.07.2005

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Vänttinen, H

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2005/000760

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 6 306 124 B1 (JONES MICHAEL L ET AL) 23 October 2001 (2001-10-23) column 3, last paragraph - column 4, paragraph 2 page 12, paragraph 1; figures 1,8 -----	1-4,6,8, 10-17
X	US 4 447 237 A (FRISCH ET AL) 8 May 1984 (1984-05-08)	14
Y	column 3, last paragraph - column 4, paragraph 1 column 12, paragraph 2; figures -----	1-4,6,8, 10-17
A	WO 92/06732 A (STRATO MEDICAL CORPORATION) 30 April 1992 (1992-04-30)  abstract; claims; figures -----	1,3,4, 10,11, 13-16

# INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US2005/000760

## Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☐ Claims Nos.:  
because they relate to subject matter not required to be searched by this Authority, namely:
2. ☐ Claims Nos.:  
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
3. ☐ Claims Nos.:  
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

## Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-17

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. claims: 1-17

Pressure activated valve having a nonthrombogenic coating on fluid contacting surfaces or a catheter having such a valve

---

2. claims: 18-21

Pressure activated valve having a plurality of flexible members stacked on one another

---

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2005/000760

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9723255	A	03-07-1997	FR 2742665 A1 EP 0810891 A1 WO 9723255 A1 US 5984903 A	27-06-1997 10-12-1997 03-07-1997 16-11-1999
WO 9726931	A	31-07-1997	US 5634913 A AU 708891 B2 AU 1573897 A CA 2244225 A1 CN 1213319 A EP 0876172 A1 JP 2000504246 T WO 9726931 A1	03-06-1997 12-08-1999 20-08-1997 31-07-1997 07-04-1999 11-11-1998 11-04-2000 31-07-1997
US 6152909	A	28-11-2000	US 5833644 A AU 6347798 A EP 1011775 A1 WO 9839047 A1 US 6398773 B1 AU 6450198 A WO 9838930 A1 US 6849068 B1 US 2002035347 A1 AU 6688398 A CA 2322876 A1 US 2002062119 A1 US 6135991 A WO 9838929 A1 US 2003055398 A1 US 2003009146 A1 US 6652480 B1 US 6454741 B1 AT 262945 T AT 285812 T AU 3071797 A AU 3071897 A AU 3132097 A CA 2255684 A1 CA 2256401 A1 DE 69728390 D1 DE 69728390 T2 DE 69732104 D1 EP 0904125 A2 EP 0901392 A2 EP 0906135 A2 JP 2001508670 T JP 2001517970 T JP 2000511082 T US 2002133117 A1 US 2002052638 A1 US 6312407 B1 US 2002091407 A1 US 6355014 B1 US 6544276 B1 WO 9744082 A2 WO 9744084 A2 WO 9744085 A2 US 6464816 B1	10-11-1998 22-09-1998 28-06-2000 11-09-1998 04-06-2002 22-09-1998 11-09-1998 01-02-2005 21-03-2002 22-09-1998 11-09-1998 23-05-2002 24-10-2000 11-09-1998 20-03-2003 09-01-2003 25-11-2003 24-09-2002 15-04-2004 15-01-2005 09-12-1997 09-12-1997 09-12-1997 27-11-1997 27-11-1997 06-05-2004 10-03-2005 03-02-2005 31-03-1999 17-03-1999 07-04-1999 03-07-2001 09-10-2001 29-08-2000 19-09-2002 02-05-2002 06-11-2001 11-07-2002 12-03-2002 08-04-2003 27-11-1997 27-11-1997 27-11-1997 15-10-2002

## INTERNATIONAL SEARCH REPORT

International Application No

PCT/US2005/000760

Patent document cited in search report	Publication date	Patent family member(s)	Publication date	
US 6152909	A	US 6325777 B1	04-12-2001	
		US 6325778 B1	04-12-2001	
		US 2004015150 A1	22-01-2004	
-----				
US 6306124	B1	23-10-2001	US 6254588 B1	03-07-2001
			US 5843050 A	01-12-1998
			AU 1051897 A	05-06-1997
			CA 2234706 A1	22-05-1997
			EP 0861100 A1	02-09-1998
			JP 2000500366 T	18-01-2000
			WO 9717998 A1	22-05-1997
-----				
US 4447237	A	08-05-1984	JP 58168333 U	10-11-1983
-----				
WO 9206732	A	30-04-1992	US 5156600 A	20-10-1992
			AT 127027 T	15-09-1995
			AU 653973 B2	20-10-1994
			AU 8911691 A	20-05-1992
			CA 2091561 A1	11-04-1992
			DE 9190142 U1	03-06-1993
			DE 69112632 D1	05-10-1995
			DE 69112632 T2	08-02-1996
			DK 552313 T3	08-01-1996
			EP 0552313 A1	28-07-1993
			ES 2076744 T3	01-11-1995
			GR 3017489 T3	31-12-1995
			JP 7108320 B	22-11-1995
			JP 5505966 T	02-09-1993
			WO 9206732 A1	30-04-1992
-----				

# PATENT COOPERATION TREATY

REC'D 21 JUL 2005

WIPO

PCT

From the  
INTERNATIONAL SEARCHING AUTHORITY

## PCT

To:

see form PCT/ISA/220

### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/US2005/000760

International filing date (day/month/year)  
14.01.2005

Priority date (day/month/year)  
29.01.2004

International Patent Classification (IPC) or both national classification and IPC  
A61M39/22, A61M39/24, A61M25/00

Applicant  
BOSTON SCIENTIFIC SCIMED, INC.

#### 1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

#### 2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1b/s(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

#### 3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office  
D-80293 Munich  
Tel. +49 89 2399 - 0 Tx: 523656 epmu d  
Fax: +49 89 2399 - 4465

Authorized Officer

Vänttinen, H

Telephone No. +49 89 2399-7442



**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2005/000760

---

**Box No. I Basis of the opinion**

---

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
  - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:
    - ☐ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material:
    - ☐ in written format
    - ☐ in computer readable form
  - c. time of filing/furnishing:
    - ☐ contained in the international application as filed.
    - ☐ filed together with the international application in computer readable form.
    - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:



**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2005/000760

---

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

---

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 18-21

because:

- ☐ the said international application, or the said claims Nos.     relate to the following subject matter which does not require an international preliminary examination (*specify*):
- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos.     are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for the whole application or for said claims Nos. 18-21
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
  - the written form                      ☐ has not been furnished
  - ☐ does not comply with the standard
  - the computer readable form       ☐ has not been furnished
  - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/US2005/000760

---

**Box No. IV Lack of unity of invention**

---

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees, the applicant has:
- ☐ paid additional fees.
  - ☐ paid additional fees under protest.
  - ☒ not paid additional fees.
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.
3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is
- ☐ complied with
  - ☒ not complied with for the following reasons:  
**see separate sheet**
4. Consequently, this report has been established in respect of the following parts of the international application:
- ☐ all parts.
  - ☒ the parts relating to claims Nos. 1-17

---

**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

---

1. Statement

Novelty (N)	Yes: Claims	1-9,11-13,15-17
	No: Claims	10,14
Inventive step (IS)	Yes: Claims	7,9
	No: Claims	1-6,8,10-17
Industrial applicability (IA)	Yes: Claims	1-17
	No: Claims	

2. Citations and explanations

**see separate sheet**

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

---

International application No.  
PCT/US2005/000760

---

**Box No. VII    Certain defects in the international application**

---

The following defects in the form or contents of the international application have been noted:

**see separate sheet**

**1 Concerning Item IV**

In the light of WO-A-97/23255 (D1), being considered as the closest prior art, claims 1, 10 and 14 have a common special technical feature, namely that the valve has a nonthrombogenic coating (see Item V). Since other technical features of claims 1, 10 and 14 are known from D1 and claim 18 does not include a technical feature corresponding to the special technical feature of the other independent claims, claim 18 is not so linked as to form a single general inventive concept with the remaining independent claims. Hence, said claims lack unity and are considered to relate to two possible groups of inventions as indicated below. The separate inventions/groups of inventions are:

Claims 1-17: Pressure activated valve having a nonthrombogenic coating on fluid contacting surfaces or a catheter having such a valve

Claims 18-21: Pressure activated valve having a plurality of flexible members stacked on one another

**2 Concerning Item V.**

- 2.1 D1 discloses a catheter comprising a lumen (9) and a valve (5) having a flexible membrane (17) including a slit (7).
- 2.2 In the light of D1, the subject-matter of claim 1 is considered to differ from the disclosure of D1 by that the valve has a nonthrombogenic coating. WO-A-97/26931 (D2) discloses a medical device having a valve structure including an antithrombogenic agent for preventing the clotting of blood. Consequently, in the light of the teaching of D2, it would be obvious for the skilled person to arrive at the subject-matter of claims 1 and 6, should he face the problem of preventing clotting of blood at the valve of D1. Thus, the subject-matter of claim 1 does not meet the requirement of Article 33(3) PCT.
- 2.3 In addition, the technical features of dependent claims 2-4 and 8 appear to be disclosed by D1 and the technical feature of claim 5 appears to be obvious from the disclosure of US-A-6 152 909 (D3). Thus, claims 2-5 and 8 do not meet the requirement of Article 33(3) PCT.

- 2.4 D2 discloses a tubular device being suitable for dialysis, comprising an elongated body (32, 46), a lumen and a valve (48) having a nonthrombogenic coating as defined in claims 10 and 14. Consequently, the subject-matters of claims 10 and 14 do not meet the requirement of Article 33(2) PCT.
- 2.5 The technical features of the dependent claims 11-13 and 15-17 appear to be obvious from the combined teaching of D1 and D2 or US-A-4 447 237 (D5). Thus, said claims do not meet the requirement of Article 33(3) PCT.
- 2.6 The technical features of claims 7 and 9 do not appear to be derivable from any of the cited documents in an obvious manner. Thus, the subject-matters of said claims appear to meet the requirements of Article 33(2) and (3) PCT.
- 2.7 The industrial applicability (Article 33(4) PCT) of a device according to the claims 1-17 is self-evident.

### **3 Concerning Item VII**

The closest prior art (D1) has not been identified as required by Rule 5(a)(ii) PCT. Furthermore, the independent claims are not in the two-part form as required by Rule 6.3(b) PCT. In addition, the claims do not include reference signs in parentheses as required by Rule 6.2(b) PCT.